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INTELLECTUAL PROPERTY LAW

PATENT TRADEMARK  
AND COPYRIGHT LAW

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May 6, 2002

**Via Facsimile Only: (703) 746-9195 - 8 pages**

Filing Receipt Corrections  
Office of Initial Patent Examination  
Commissioner for Patents and Trademarks  
Washington, DC 20231.

Re: Second Request for Corrected Filing Receipt  
D'Antonio et al. U.S. Reissue Patent Appln. 10/056,441  
Filed January 24, 2002  
HYPODERMIC FLUID DISPENSER  
Our Ref. DA9397US.CIP2RE (#90036)

Gentlemen:


This is a second request for a corrected Filing Receipt for the referenced application. A copy of the "Corrected Filing Receipt" mailed 04/25/2002 is enclosed with the previously omitted correction indicated thereon. The correction requested is the deletion of the data listed under the portion "Domestic Priority data as claimed by applicant." This deletion was part of the correction noted in our "Request for Corrected Filing Receipt" mailed March 25, 2002 (copy attached).

The deletion of the Domestic Priority data is further substantiated by the "Preliminary Amendment" filed with the application on January 24, 2002, a copy of which is also enclosed.

As this correction is not due to any error by the applicants, no fee is required.

Prompt issuance of a second Corrected Filing Receipt is requested.

Sincerely yours,

  
D. Peter Hochberg

DPH/ck  
Enc.

FAX RECEIVED  
MAY 20 2002  
GROUP 3700



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/056,441	01/24/2002	3732	370	DA9397US.CIP2 RE	23	18	2

CONFIRMATION NO. 2618

CORRECTED FILING RECEIPT



\*OC000000007958834\*

28672

D. PETER HOCHBERG CO. L.P.A.  
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CLEVELAND, OH 44114

Date Mailed: 04/25/2002

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Nicholas F. D'Antonio, Tully, NY;  
Linda F. D'Antonio, Syracuse, NY;  
John T. Wagner, Drexel Hill, PA;

## Assignment For Published Patent Application

D'Antonio Consultants International, Inc., E. Syracuse, NY;

## Domestic Priority data as claimed by applicant

~~THIS APPLICATION IS A REF OF 08/738,303 10/25/1998 PAT 5,608,716  
WHICH IS A CIP OF 08/258,446 06/03/1994 PAT 5,568,138  
WHICH IS A CIP OF 07/818,235 01/08/1992 PAT 5,318,522  
WHICH IS A CIP OF 07/856,636 04/07/1989 PAT 5,080,648  
WHICH IS A CIP OF 07/950,620 06/08/1987 ABN~~

## Foreign Applications

If Required, Foreign Filing License Granted 03/15/2002

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

**\*\* SMALL ENTITY \*\*****Title**

Hypodermic fluid dispenser

**Preliminary Class**

604

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**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

Attorney File: DA9397US.CIP2RE

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: D'Antonio et al.

Serial No. 10/056,441

Group No. 3732

Filed: January 24, 2002

Examiner:

Title: HYPODERMIC FLUID DISPENSER

Assistant Commissioner of Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, D.C. 20231

**REQUEST FOR CORRECTED FILING RECEIPT**

1. Attached is a copy of the official filing receipt received from the PTO in the above application for which issuance of a corrected filing receipt is respectfully requested.

2. There is an error in that the following data is:

- ☒ (X) incorrectly entered  
and/or
- ☒ (X) omitted
  - ☐ Applicant's name
  - ☐ Applicant's address
  - ☒ (X) Title
  - ☐ Filing Date
  - ☐ Serial No.
  - ☐ Foreign/PCT Application Reference
  - ☒ (X) Other

in that the filing receipt should read as follows: In the "Title" the "n" should be removed and replaced with an --m-- to correctly spell "Hypodermic"; and

in that there should not be any "Domestic Prior date as claimed by applicant," and that the five (5) earlier applications should be omitted.

3: (complete the following applicable item A or B)

A. (X) The correction is not due to any error by applicant and no fee is due

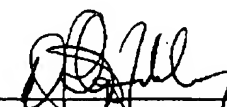
OR

B. () The correction is due to applicant's error and the fee thereof under 37  
1.19(i) of \$25.00 is paid as follows:

CFR

- ☐ enclosed is a check for \$25.00
- ☐ charge Account No. 08-2441 for \$25.00

By: \_\_\_\_\_

  
D. Peter Hochberg  
Reg. No. 24,603

Att.: Copy of Filing Receipt

D. Peter Hochberg Co., L.P.A.  
The Baker Building - Sixth Floor  
1940 East 6th Street  
Cleveland, Ohio 44114  
(216) 771-3800

### CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached hereto or transmitted herewith) is being deposited with the United States Postal Service as first class mail in an envelope addressed: Assistant Commissioner of Patents, Office of Initial Patent Examination, Customer Service Center, Washington, DC 20231

Date: \_\_\_\_\_

March 25, 2002

  
Kathi Hotchkiss

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : D'Antonio et al.  
Reissue Application No. : (Not yet available)  
Reissue of U.S. Patent No. : 6,056,716  
Issue Date : May 2, 2000  
Title : HYPODERMIC FLUID DISPENSER  
Attorney's Docket : DA9397US.CIP2RE (#90036)

Box Reissue  
Assistant Commissioner for Patents  
Washington, D.C. 20231

## PRELIMINARY AMENDMENT

Sir:

Prior to the substantive examination of the above-identified reissue application, please amend the application without prejudice as follows:

In the Specification

Column 1, lines 3-13, please delete in its entirety, from "CROSS-REFERENCE TO RELATED APPLICATION...now, abandoned."

A copy of the page containing column 1, with the deleted material cut out, in accordance with MPEP § 1410 is attached.

## REMARKS

The above-identified patent application was filed as a continuation-in-part application because neither the inventors nor the assignee had any idea that this would effect the duration of any patent that issued from the above-identified application. They had continuously believed that it would expire based on the filing date of the application since that is when the subject matter was introduced into the patent application and based upon which the claims in the application find support. The foregoing subject matter was not disclosed in any of the patent applications or patents set forth under the heading "Related U.S. Applications Data".

The assignee very recently learned that the above-identified patent would expire 20 years from the filing of its earliest filed parent application, namely U.S. Application Serial No. 07/059,620 filed on June 8, 1987, even though that patent application did not disclose the subject matter of the claims in U.S. Patent No. 6,056,716. An offer was made to purchase patent rights under U.S. Patent No. 6,056,716, which was far lower than it would have been had the patent had as

its effective filing date October 25, 1996, rather than the June 8, 1987 filing date of U.S. Serial No. 07/059,620.

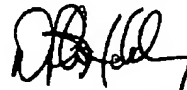
According to 35 U.S.C. 154(a)(2), about which neither the inventors nor their assignee was aware, the 20 year term of a patent is measured from an earlier-filed priority application if the application resulting in the patent "contains a specific reference" to the earlier filed application "under section 120,121,365(c)". The present patent makes reference to four earlier filed patent applications under 35 U.S.C. 120, although there was no need to make such reference (or to any of the other foregoing applications which were continuation in part applications from which patents have issued). The inventors and their assignee find this deprivation of the term of their patent rights both extremely unfair and costly.

The above-identified application claimed less than the patentee had a right to claim in the patent, by claiming the filing date of an earlier filed patent application and thus decreasing the term of the above identified patent.

It is respectfully requested that this Preliminary Amendment be entered, and that a reissue patent be granted.

The examiner is invited to telephone the undersigned if there are any issues which could be discussed to expedite the prosecution of the present reissue application.

Respectfully submitted,



D. Peter Hochberg  
Reg. No. 24,603

DPH/kh

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**EXPRESS MAIL CERTIFICATE**

Express Mail Label Number EE146639716US

MAILED: January 24, 2002

I hereby certify that the paper(s) identified above, and any noted as being attached, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed: Box Reissue, Assistant Commissioner for Patents, Washington D.C. 20231

Date

January 24, 2002

Christine Kotran

Christine Kotran

6,056,716

1

## HYPODERMIC FLUID DISPENSER

2

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

This invention relates to apparatus for the hypodermic injection of fluids.

## 2. Description of the Prior Art

Hypodermic fluid dispensers fall into two broad categories, namely, needle hypodermic dispensers and needle-less injectors, such as jet injectors. In the past, jet injectors have been particularly useful in large scale immunization programs, such as those administered by the World Health Organization (WHO) or the military, for example, where the number of subjects to be immunized in a single session is very large (more than 200 injections per session). However, in recent years, jet injectors are also finding benefit in more routine immunizations at WHO health centers around the world, where the number of subjects injected is relatively small at less than 40 injections per session.

In general, jet inoculation, as compared to needle inoculation, is less traumatic, requires less operator training, and allows a higher number of procedures per unit of time.

Although both needle hypodermic injectors and high pressure jet injectors have been widely used, the presently known devices have serious disadvantages with respect to the injection of humans and animals alike. There exists a high level of belief that conventional jet injectors are capable of cross-infection when the same orifice is used for subsequent injections, and the problems associated with needle injectors in the spread of AIDS (Acquired Immune Deficiency Syndrome) alone is sufficient motivation to avoid proliferation of today's needle systems. People cannot be relied upon to dispose of needle injectors in accordance with instructions and good practice, and an element of the population are tempted to reuse needles without knowledge of or regard for safe practices.

There are other important shortcomings in the present state of the art with respect to the inoculation of humans and large animals, such as cattle and pigs. In the case of large animals, needles used for injecting vaccines, vitamins, medications and hormones in large, food-producing animals often cause damage to prime portions of the meat through the creation of abscesses and scars, resulting in serious economic loss to the industry. In the majority of cases, these factors are even more prevalent because the needle injectors become dull or bent when used for multiple injections, which is a common practice in the industry. In addition, due to increased awareness of cross-infection in food-producing animals, agricultural leaders recommend that needles no longer be reused for animal injections. Furthermore, it is not at all unusual for multiple injections to be scheduled within the same period of time, this being true for humans and animals as well. However, repeated injections are usually

met with greater resistance by the recipient and also makes the procedure far more expensive. Hence, other important shortcomings would be overcome if more than one material could be injected at the same time.

Properly configured jet injectors provide the best chance for reducing the problems of cross-contamination, as well as the case where more than one injection is required at the same time, and could reduce the time to train people involved in the injection process. If jet injectors were effective for both animals and humans, a higher number of procedures per unit of time would be possible. The higher number of procedures is particularly important in the beef and dairy industry where each day a certain number of animals receive injections. This is also true for the multiple vaccine requirement for children.

Large animal hide, such as cowhide, can be very thick, often in the range of  $\frac{1}{8}$  inch to  $\frac{3}{8}$  inch or more in thickness. The hide includes the hair, a tough outer layer, and thereafter the dermis, whose inside surface has a rubber-like interface that begins the subcutaneous ("sub-Q") layer that separates the hide and the muscle. In cattle, injections are usually given in the neck, a leg or a hind quarter. A known CO<sub>2</sub>-driven jet injector was experimentally tested on a freshly euthanized cow and the injection site was immediately followed by a pathologist's examination. It was found that the injection rarely penetrated the desired depth into the muscle.

Electrically operated needle-less injectors, previously disclosed, often require standard batteries, since standard power sources are not available at remote or isolated areas where injections are often given. People responsible for the immunization programs at these locations are concerned about disposal of these batteries, leading to the recommendation that rechargeable batteries be used. Indeed, the use of any electrically-powered injector used away from standard power sources would be enhanced if there were no batteries to be disposed of, yet sufficient electrical power were available.

The exit path of needle-less injectors, referred to as "orifices," present additional problems. Orifices are commonly found in the range of 0.004 to 0.014 inches. Extensive experimentation has shown that these orifices are likely to be ineffective for deep injections unless virtually perfect in structure and optimized in diameter for that particular injection site. If the orifices are poorly configured, they will fail to penetrate the thick hide of an animal, and satisfactory deep injections will not occur no matter what pressure is applied on the serum or other product being injected. When poorly configured orifices with diameters in the range of 0.004 to 0.014 inches are used with injection pressures as high as 2,000 to 10,000 psi, effective deep injections have not been possible.

It is important that the speed at which needle-less injections are made is high, whereby the entire dose, or doses, enters the animal's body quickly by way of the high velocity jet stream. Movement could cause a loss of the initial penetration point and the injection could fail. As noted above with respect to cows, the injection must clear a hide thickness of  $\frac{3}{8}$  inch, or more in some cases, to achieve intramuscular ("IM") injection. Speed of injection, orifice size, quality of the jet stream, and lack of movement are necessary to get good IM injection results. If any of these characteristics are not fully met, or if the jet stream breaks down when the injection material is designed for an IM injection, the fluid will remain in the dermis, or in the subcutaneous layer instead, and could result in a less-effective or even a totally useless injection.





## UNITED STATES PATENT AND TRADEMARK OFFICE

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WASHINGTON, D.C. 20231  
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Bib Data Sheet

CONFIRMATION NO. 2618

<b>SERIAL NUMBER</b> 10/056,441	<b>FILING DATE</b> 01/24/2002 <b>RULE</b>	<b>CLASS</b> 604	<b>GROUP ART UNIT</b> 3732	<b>ATTORNEY DOCKET NO.</b> DA9397US.CIP2 RE
<b>APPLICANTS</b> Nicholas F. D'Antonio, Tully, NY; Linda F. D'Antonio, Syracuse, NY; John T. Wagner, Drexel Hill, PA;				
<b>** CONTINUING DATA *****</b> <b>** FOREIGN APPLICATIONS *****</b>				
<b>IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY **</b> ** 03/15/2002				
Foreign Priority claimed <input type="checkbox"/> yes <input type="checkbox"/> no 35 USC 119 (a-d) conditions met <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after Allowance Verified and Acknowledged _____ Examiner's Signature _____ Initials _____		<b>STATE OR COUNTRY</b> NY	<b>SHEETS DRAWING</b> 23	<b>TOTAL CLAIMS</b> 18
<b>INDEPENDENT CLAIMS</b> 2				
<b>ADDRESS</b> 28672				
<b>TITLE</b> Hypodermic fluid dispenser				
<b>FILING FEE RECEIVED</b> 370	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees ( Filing ) <input type="checkbox"/> 1.17 Fees ( Processing Ext. of time ) <input type="checkbox"/> 1.18 Fees ( Issue ) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit	

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MAY 20 2002

GROUP 3700